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June 6, 2005

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1635**

Re: U.S. Utility Patent Application  
Application No. 10/725,015; Filed: December 2, 2003  
For: **Method for Producing Sterile Polynucleotide Based Medicaments**  
Inventors: GEALL *et al.*  
Our Ref: 1530.0610001/EKS/J-H

Sir:

Transmitted herewith for appropriate action are the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement under 37 C.F.R. § 1.97(b);
3. Form PTO-1449, 3 pages, listing 40 documents (AA1-AE3, AL1-AM2 and AR1-AT2);
4. One (1) copy of the 13 cited documents (AL1-AM2 and AR1-AT2); and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
June 6, 2005  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

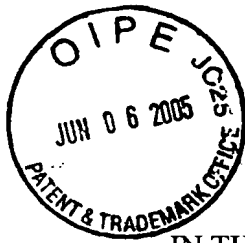
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Eric K. Steffe  
Attorney for Applicants  
Registration No. 36,688

EKS/J-H/tis:awt

368358v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Geall *et al.*

Appl. No.: 10/725,015

Filed: December 2, 2003

For: **Method for Producing Sterile  
Polynucleotide Based  
Medicaments**

Confirmation No.: 3181

Art Unit: 1635

Examiner: *Schnizer, R. A.*

Atty. Docket: 1530.0610001/EKS/J-H

**Information Disclosure Statement Under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents, **AL1** to **AM2** and **AR1** to **AT2** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents AA1 to AD3, cited on the attached Form PTO-1449 are not submitted.

The Examiner's attention is directed to the following co-pending, related applications:

U.S. Application No. 09/839,574, inventors Manthorpe *et al.*, filed April 23, 2001, now published as U.S. Publication No. 2002/0019358 A1 (Document **AI2**)

U.S. Application No. 10/202,858, inventors Felgner *et al.*, filed July 26, 2002, now published as U.S. Publication No. 2003/0032615 A1 (Document **AJ2**);

U.S. Application No. 10/360,645, inventors Wolff *et al.*, filed February 10, 2003, now published as U.S. Publication No. 2003/0186913 A1 (Document **AK2**);

U.S. Application No. 10/391,216, inventor Wheeler, C.J., filed March 19, 2003, now published as U.S. Publication No. 2003/0191082 A1 (Document **AC2**);

U.S. Application No. 10/127,683, inventors Hobart *et al.*, filed April 23, 2002, now published as U.S. Publication No. 2003/0203863 A1 (Document **AD2**);

U.S. Application No. 10/725,009, inventor Geall, A., filed December 2, 2003, now published as U.S. Publication No. 2004/0157789 A1 (Document **AE2**);

U.S. Application No. 10/748,853, inventor Wheeler, C.J., filed December 30, 2003, now published as U.S. Publication No. 2004/0171572 A1 (Document **AF2**);

U.S. Application No. 10/738,986, inventors Hermanson *et al.*, filed December 19, 2003, now published as U.S. Publication No. 2004/0209241 A1 (Document **AG2**);

U.S. Application No. 09/937,604, inventor Wheeler, C.J., which is the U.S. National Phase of International Appl. No. PCT/US00/08282 (WIPO Publication No. 00/57917 A2) (Document **AL2**), having a 35 U.S.C. §371 date of September 26, 2001;

U.S. Application No. 09/478,457, inventors Wolff *et al.*, filed January 6, 2000, now pending (Document **AS2**);

U.S. Application No. 10/658,688, inventor Hermanson, G.G., filed September 10, 2003, now pending;

U.S. Application No. 10/843,656, inventors Vilalta *et al.*, filed May 12, 2004, now pending;

U.S. Application No. 60/571,854, inventors Luke *et al.*, filed May 18, 2004, now pending; and

U.S. Application No. 60/632,612, inventor Geall A., filed December 3, 2004, now pending;

which are directed to related technical subject matter. Copies of co-pending U.S. Application Nos: 10/658,688, 10/843,656, 60/571,854 and 60/632,612 are not provided pursuant to the Waiver of Requirements in 37 C.F.R. § 1.98, *Official Gazette*, October 16, 2004. A copy of co-pending U.S. Application No. 09/478,457 is provided as the application is not available electronically via the United States Patent and Trademark Office Image File Wrapper System (IFW). The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits that document **AT1** is in a foreign language. The relevance of document **AT1** may be found in the English language abstract included therein.

The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the

effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

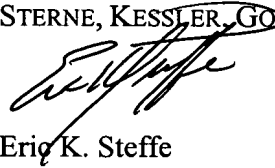
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

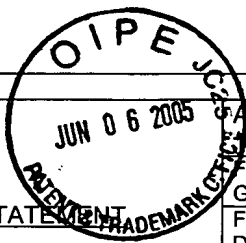


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Date:

6/6/05

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 530.0610001/EKS/J-H		APPLICATION NO. 10/725,015
FIRST NAMED INVENTOR Geall <i>et al.</i>		
FILING DATE December 2, 2003	ART UNIT 1635	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,264,618	11/23/1993	Felgner <i>et al.</i>			04/16/1991
	AB1	5,459,127	10/17/1995	Felgner <i>et al.</i>			09/16/1993
	AC1	5,567,859	10/22/1996	Emanuele <i>et al.</i>			08/09/1994
	AD1	5,656,611	08/12/1997	Kabanov <i>et al.</i>			11/18/1984
	AE1	5,674,911	10/07/1997	Emanuele <i>et al.</i>			06/06/1995
	AF1	5,696,298	12/09/1997	Emanuele <i>et al.</i>			06/02/1995
	AG1	5,990,241	11/23/1999	Emanuele <i>et al.</i>			07/08/1997
	AH1	6,359,054 B1	03/19/2002	Lemieux <i>et al.</i>			01/08/1999
	AI1	6,586,409 B1	07/01/2003	Wheeler			03/24/2000
	AJ1	6,147,055	11/14/2000	Hobart <i>et al.</i>			03/14/1997
	AK1	5,703,055	12/30/1997	Felgner <i>et al.</i>			01/26/1994

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 96/04392 A2	02/15/1996	WIPO			Yes No
	AM1	WO 96/04932 A1	02/22/1996	WIPO			Yes No
	AN1	WO 97/40839 A1	11/06/1997	WIPO			Yes No
	AO1	WO 99/06055 A1	02/11/1999	WIPO			Yes No
	AP1	WO 99/21591 A1	05/06/1999	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Newman, M.J., <i>et al.</i> , "Use of Nonionic Block Copolymers in Vaccines and Therapeutics," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> 15:89-142, Begell House, Inc. (1998)
	AS	1	Todd, C.W., <i>et al.</i> , "Systematic Development of a Block Copolymer Adjuvant for Trivalent Influenza Virus Vaccine," <i>Dev. Biol. Stand.</i> 92341-351, Karger (1998)
	AT	1	Tse, C. and Capeau, J., "Quantification des acides nucléiques par PCR quantitative en temps réel," <i>Ann. Biol. Clin.</i> 61:279-293, John Libbet Eurotext (May-June 2003)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 1530.0610001/EKS/J-H	APPLICATION NO. 10/725,015
	FIRST NAMED INVENTOR Geall <i>et al.</i>	
	FILING DATE December 2, 2003	ART UNIT 1635

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	6,670,332 B1	12/30/2003	Wheeler			06/05/98
	AB2	6,399,588 B1	06/04/2002	Hobart <i>et al.</i>			07/28/2000
	AC2	2003/0191082 A1	10/09/2003	Wheeler			03/19/2003
	AD2	2003/0203863 A1	10/30/2003	Hobart <i>et al.</i>			04/23/2002
	AE2	2004/0157789 A1	08/12/2004	Geall			12/02/2003
	AF2	2004/0171572 A1	09/02/2004	Wheeler			12/30/2003
	AG2	2004/0209241 A1	10/21/2004	Hermanson <i>et al.</i>			12/19/2003
	AH2	RE 36,665	04/18/2000	Emanuele <i>et al.</i>			06/02/1998
	AI2	2002/0019358 A1	02/14/2002	Manthorpe <i>et al.</i>			04/23/2001
	AJ2	2003/0032615 A1	02/13/2003	Felgner <i>et al.</i>			07/26/2002
	AK2	2003/0186913 A1	10/02/2003	Wolff <i>et al.</i>			02/10/2003

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 00/57917 A2	10/05/2000	WIPO			Yes No
	AM2	WO 02/00844 A2	01/03/2002	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>2</u>	Wade, A. and Weller, P.J., eds., "Benzalkonium Chloride," "Benzethonium Chloride," "Cetrimide," in: <i>Handbook of Pharmaceutical Excipients</i> , American Pharmaceutical Association, Washington, DC, pp.27-31, 96-98 (1994)
AS	<u>2</u>	Copy of Co-Pending U.S. Patent Application No. 09/478,457, Wolff <i>et al.</i> , filed January 6, 2000 (NOT PUBLISHED)
AT	<u>2</u>	Todd, C.W., <i>et al.</i> , "Development of an adjuvant-active nonionic block copolymer for use in oil-free subunit vaccines formulations," <i>Vaccine</i> 15:564-570, Elsevier Science Ltd. (1997)

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
1530.0610001/EKS/J-HAPPLICATION NO.  
10/725,015FIRST NAMED INVENTOR  
Geall *et al.*FILING DATE  
December 2, 2003ART UNIT  
1635**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	6,482,518 B1	11/19/02	Short <i>et al.</i>			07/30/1999
	AB3	5,994,314	11/30/1999	Wheeler			04/09/1996
	AC3	6,251,599 B1	06/26/2001	Chen <i>et al.</i>			11/06/1998
	AD3	5,691,387	11/25/1997	Emanuele <i>et al.</i>			06/03/1996
	AE3	6,867,195 B1	03/15/2005	Felgner <i>et al.</i>			06/07/1995
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

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	AT		

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